

PATENT COOPERATION T EATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/009619

International filing date (day/month/year)
29.03.2004

Priority date (day/month/year)
28.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61B18/14

Applicant
C.R. BARD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. ✓

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Mayer-Martenson, E

Telephone No. +31 70 340-4401



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 7-62

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 7-62 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
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International application No.
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2
	No: Claims	1,3-6
Inventive step (IS)	Yes: Claims	2
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-6
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The various definitions of the subject-matter given in the plurality of independent claims, each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as a whole are not clear and concise. The requirements of Article 6 PCT, therefore, are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Rule 43bis PCT should be based.

Therefore, this presentation of a number of independent claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden to others seeking to establish the extent of monopoly requested.

For this reason a full substantive preliminary examination cannot be carried out until the claims meet Article 6 PCT.

In the following an opinion will be given only on the first device and method claims.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: US.2002/002329 A1 (AVITALL BOAZ) 3 January 2002 (2002-01-03)
- D2: US-A-6 071 277 (FARLEY BRIAN E ET AL) 6 June 2000 (2000-06-06)
- D3: US-A-5 098 431 (RYDELL MARK A) 24 March 1992 (1992-03-24)

V.1 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 4 is not new in the sense of Article 33(2) PCT.

V.1.1 The document D1 discloses (the references in parentheses applying to this document):

*a catheter for ablating tissue, comprising:
a shaft (142) for positioning an ablation ring electrode (143) in contact with or near a tissue surface; and
an ablation ring electrode (143) disposed on the shaft; wherein
a distance from the shaft near the ablation ring electrode to the tissue surface is adjustable (cf. par.74,75)*

Also D2 discloses all features of claim 1.

In D1 the distance is adjustable by bending the catheter towards or away from tissue. In D2 inflation of the balloon increases the distance between ring electrode and tissue. In fact, every catheter bearing a ring electrode possesses the features of claim 1, because the distance can be adjusted by holding the catheter as a whole closer to or further away from tissue.

Therefore claim 1 is not new.

V.1.2 For similar reasons also claim 4 is not new.

V.2 Dependent claims

V.2.1 The combination of the features of dependent claim 2 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

D3 is considered the closest prior art and discloses:
a rotatable electrode (36) with an annular electrode surface (40) mounted
eccentrically on the shaft (12) (cf. col. 3 l.28-51; fig. 2);

The subject matter of claim 2 differs from D3 in that the ring electrode is adapted to change a distance between the shaft and tissue when rotated.

In D3 the ring like electrode is rotatably mounted such that rotation changes the distance between the second electrode surface 34 and as such also the distance between the electrode surface 40 and tissue. D3 does not disclose or fairly suggest that the distance between the shaft close to the electrode and the tissue can be adjusted by rotation of the electrode.

No other document cited shows such an arrangement, therefore the subject matter of claim 2 is new and involves an inventive step.

V.2.2 The subject matter of dependent claims 3,5,6 is not new in view of D3 and the reasons given under § V.1.1.